(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 097 728 A1

(12) EUROPEAN PATENT APPLICATION

published in accordance with Art. 158(3) EPC

(43) Date of publication:
09.05.2001 Bulletin 2001/19

(21) Application number: **99905292.1**

(22) Date of filing: **24.02.1999**

(51) Int. Cl.[7]: **A61M 29/00**

(86) International application number:
PCT/JP99/00824

(87) International publication number:
WO 00/02615 (20.01.2000 Gazette 2000/03)

(84) Designated Contracting States:
DE FR GB

(30) Priority: **10.07.1998 JP 19555898**

(71) Applicant: **Ishimaru, Shin**
Tokyo 150-0001 (JP)

(72) Inventor: **Ishimaru, Shin**
Tokyo 150-0001 (JP)

(74) Representative:
Kaminski, Susanne, Dr.
Büchel, Kaminski & Partner Patentanwälte Est.,
Letzanaweg 25-27
9495 Triesen (LI)

(54) STENT (OR STENT GRAFT) INDWELLING DEVICE

(57) A stent (or stent graft) locating device 10 comprises a number of leading wires 1, a pushing rod 6 for holding the number of leading wires in its circumferential direction and a sheath 7 for loading the pushing rod 6. The pushing rod is composed of an inner tube 6A and an outer tube 6B, a hollow portion of said inner tube is used as a guiding wire channel and another sectional ring-shaped hollow portion between said inner tube and said outer tube is used as a leading wire channel 6D. The pushing rod may be constructed of a single tube , a hollow portion of said tube is used as a guiding wire channel 6b, 6C and a plurality of leading wire channels 6c are arranged in a body of said tube at approximate regular intervals in its circumferential direction. The pushing rod 6 may have a plurality of leading wires 1 which are scattered at approximate regular intervals in the circumferential direction, a plurality of crossing leading wires 2 which are scattered in the circumferential direction, or a plurality of leading wires 1 and a plurality of auxiliary leading wires 3 which are scattered at approximate regular intervals in the circumferential direction. These wires are derived from the tip of a leading wire channel(s) 6D, 6c. The pushing rod may have plural lead-in wires 5 which are derived from the tip of the leading wire channel and engaged with the knees 11a at the terminal of the stent at approximate regular intervals by detachable engaging means (5a, 5b).

FIG. 1A

FIG. 1B

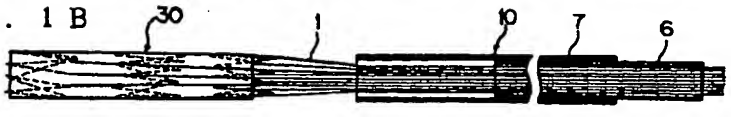

FIG. 1C

EP 1 097 728 A1

Description

(Technical Field)

[0001] This invention relates to a stent locating device for safely locating a stent (or stent graft) at a diseased part in order to treat a stenotic and expansive disease (aneurysm) of an artery and other diseases.

(Background Art)

[0002] The aneurysm which grows owing to hardening or inflammation of the artery, when left, expands gradually and ruptures fatally to reach a disease with no prognosis. Medicine treatment does not almost have an effect on this disease. Therefore, in order to cure the aneurysm, traditionally, a surgical operation using an artificial brood vessel, e.g. an operation of removing a cancer tissue and of replacement has been performed. However, this disease is often suffered by old persons, thus providing strong likelihood of causing multiple organ failure (disorder of the brain, heart or kidney, etc.). In addition, the surgical operation often provides excessive invasion. Thus, the surgical operation for this disease is limited to safe technique which can avoid the danger of these difficulties. Accordingly, much attention has been paid in the world to the application of the treatment in the blood vessel using a catheter which is relatively right in operational invasion. The treatment using the stent is also expected as one of these applications.

[0003] The stent is an artificial tubular structure to be inserted into an internal tubular organ such as a blood vessel for the purpose of supporting it. When the internal tube such as a blood vessel, gallbladder, esophagus, intestines, urethra, etc. suffers stenosis or deformation, the stent is inserted into the internal tube to support it so that the stenosis and deformation are prevented. The stent which has been widely applied crinically in order to cure an arterial stenotic disease is a cylinder in the form of a wire mesh or spring made of stainless steel or shape memory alloy (NiTi). The cylinder is formed to be shrinkable or expandable repeatedly in a radial direction. The stent graft is a blood-vessel inserted-type artificial blood vessel in which the above cylinder formed of the mesh or spring made of stainless or nickel titanium is sewed into the artificial vessel made of polyester or Teflon. The stent graft has been effectively used to treat the aneurysm. Such a stent (or stent graft) is known in e.g. JP-A-7-24072, JP-A-7-47134, JP-A-7-500272 (PCT) , JP-A-8-299456 (PCT), JP-A-8-502428 (PCT) and JP-A-8-511487 (PCT).

[0004] Such a stent (or stent graft) is located on the diseased part of a blood vessel through a catheter. Specifically, the stent (or) is compressed to have a diameter smaller than the inner diameter of a fine catheter and is housed in the catheter. The stent is inserted from the incised part of a peripheral artery (mainly femoral artery) into the diseased part of the blood vessel. In this case, the stent (or stent graft) is extruded from the catheter to expand to a prescribed diameter in a radial direction. The stent is further located at the diseased part of the blood vessel, thereby expanding an artery stenotic disease and closing the aneurysm while reconstructing a bloodstream. The treatment using the stent (or stent graft) is right in the operation invasion. Therefore, it can lighten the burden imposed on a patient, and can be also applied to the aneurysm disease to which it has not been applied. Thus, this treatment is an effective for the patient suffering from the arterial stenotic disease and expansive disease.

[0005] However, the conventional stent (or stent graft) cannot be contracted again after it has been discharged from a catheter to expand and located in the blood vessel. Therefore, where the disorder of the blood stream and internal organ happen because of erroneous positioning of the stent, it cannot be moved or recovered.

[0006] Further, in order to close the aneurysm surely, the conventional stent graft must be located over the wider range including not only the part of aneurysm but also the normal artery on the central and peripheral sides so that the contact between the stent graft and the internal face of the artery is assured. However, in this case, there was a problem that the stent graft also closes the main artery which branches from the vicinity of the aneurysm to generate organ disorder (hereinafter referred to as "position abnormality"). For example, an abdominal aortic aneurysm, when the artery such as a renal artery, inferior mesenteric artery, internal iliac artery, etc. is closed, will be attacked by renal failure or colon ischemia. A thoracic aortic aneurysm, when an intercostal artery is closed, may be attacked by spinal cord ischemia, leading to serious complication of paralysis of a lower half of a body.

[0007] The inventor of this invention supposed as follows. It is assumed that a stent (or stent graft) which can recovered from the body is previously located temporarily at the diseased part of a blood vessel before the conventional stent (or stent graft) is located at the diseased part. In this case, if a dangerous part where the bloodstream disorder may happen when the conventional stent (or stent graft) is located in the blood vessel and a safe part where no bloodstream disorder happens are taken beforehand as video information, the conventional stent can be located at the safe point of the diseased part in the blood vessel. On the basis of this idea, the inventor of this invention proposed a temporarily locating type stent (or stent graft) which can be recovered from the body after it is temporarily located (JP application No. 9-151372.

[0008] Hereinafter, in the specification, a stent (or stent graft) which can be located temporarily at a diseased part is referred to as "temporarily locating type stent (or stent graft)". On the other hand, the conventional stent (or stent graft), which is permanently located at the diseased part, should be referred to as "perma-

nently locating type stent (or stent graft), but will be referred to as simply "stent (or stent graft)" as called traditionally except that it is necessary to discriminate these stents from each other particularly.

[0009] In Fig. 12, reference numeral 111 denotes a temporarily locating type stent proposed by the inventor of this invention. The temporarily locating type stent 111 is composed of a stent body 112 at the front and mast lines 118 at the rear. The stent body 112 has three elastic rings 114 each formed in ring shape by a metallic wire bent in zigzag. Each elastic ring 114 is made of stainless steel, titanium, shape memory alloy, etc. Around the elastic ring 114, eight coupling wires 115 are arranged at regular intervals in a circumferential direction of the ring. These coupling wires 115 are welded or soldered on the elastic rings 114 at their points of intersection of them to form an elastic cylindrical body 114. The elastic cylindrical body 113 is successive to parallel portions 116 of the coupling wires 115. The mast lines 118 whose tips 119 are connected to the parallel portions 116 in the stent body 112 extend rearward in their bundle. The coupling wires 115 and mast wires 118 are made of continuous shape memory alloy. The bundle of the mast wires 118 has a diameter which is slightly smaller than the inner diameter of a catheter 131. The mast wires 118 have a length enough to penetrate through the catheter 131 and to be operable outside the body when the stent body 112 is located at a prescribed position in a blood vessel. The stent body 112 and the mast wires 118 have rigidity enough to endure extrusion from the catheter 131 by the operation from outside of the body and the pull-in into the catheter 131. The catheter 131 is equipped, at its outlet, with an R-shape so that the stent body 112 can be contracted smoothly and received in the body.

[0010] The temporarily locating type stent (or stent graft), when it is used for testing, makes it possible to catch beforehand, as video information, the dangerous part where the bloodstream disorder may happen in the diseased part in e.g. the blood vessel and a safe part where no bloodstream disorder happens. This temporarily locating type stent permits the permanent locating type stent to be located on the safe point of the diseased part. However, the temporarily locating type stent takes a long time for testing so that a patient is caused pain or burden, and the testing is costly.

[0011] The present invention intends to solve these problems.

[0012] More specifically, the present invention intends to provide a device for locating a stent (or stent graft) which can locate the stent (or stent graft) at a diseased part safely, and reduce pain or burden for a patient and the cost required for testing.

[Disclosure of Invention]

[0013] In order to attain the above object, the invention defined in claim 1 is a stent (or stent graft) locating device comprising a number of leading wires, a pushing rod for holding the number of leading wires in its circumferential direction and a sheath for loading the pushing rod therein.

[0014] The invention defined in claim 2 is a stent (or stent graft) locating device according to claim 1, wherein said pushing rod is composed of an inner tube and an outer tube, a hollow portion of said inner tube is used as a guiding wire channel and another sectional ring-shaped hollow portion between said inner tube and said outer tube is used as a leading wire channel.

[0015] The invention defined in claim 3 is a stent (or stent graft) locating device according to claim 1, wherein said pushing rod is constructed of a single tube, a hollow portion of said tube is used as a guiding wire channel and a plurality of leading wire channels are arranged in a body of said tube at approximate regular intervals in its circumferential direction.

[0016] The invention defined in claim 4 is a stent (or stent graft) locating device according to claim 1, 2 or 3, wherein said pushing rod has a plurality of leading wires which are derived from the tip of a leading wire channel and scattered at approximate regular intervals in the circumferential direction.

[0017] The invention defined in claim 5 is a stent (or stent graft) locating device according to claim 1, 2 or 3, wherein said pushing rod has a plurality of leading wires which are derived from the tip of a leading wire channel and scattered at approximate regular intervals in the circumferential direction, and said plurality of leading wires cross in the vicinity of the tip of said pushing rod so as to form a coarse mesh.

[0018] The invention defined in claim 6 is a stent (or stent graft) locating device according to claim 4 or 5, wherein said pushing rod has a plurality of auxiliary leading wires which are finer and shorter than the leading wires are derived, among the number of leading wires, from the tip of said leading wire channel.

[0019] The invention defined in claim 7 is a stent (or stent graft) locating device according to claim 4, 5 or 6, wherein said pushing rod has plural lead-in wires which are derived from the tip of the leading wire channel and engaged with the knees at the terminal of the stent at approximate regular intervals by detachable engaging means.

[0020] The invention defined in claim 8 is a stent (or stent graft) locating device according to claim 7, wherein said engaging means is a hook formed by bending the tip of each of said lead-in wires.

[0021] The invention defined in claim 9 is a stent (or stent graft) locating device according to claim 7, wherein said engaging means is a ring screwed into the tip of each of said lead-in wires.

[0022] The invention defined in claim 10 is a stent (or stent graft) locating device according to any one of claims 1 to 9, wherein said leading wires are metallic wires of stainless steel, titanium nickel or nickel.

[0023] The invention defined in claim 11 is a stent

(or stent graft) locating device according to claim 6, wherein said auxiliary leading wires are metallic wires of stainless steel, titanium nickel or nickel.

[0024] The invention defined in claim 12 is a stent (or stent graft) locating device according to any one of claims 7 to 9, wherein said lead-in wires are metallic wires of stainless steel, titanium nickel or nickel.

[0025] The invention defined in claim 13 is a stent (or stent graft) locating device according to any one of claims 1 to 12, wherein said stent (or stent graft) is encircled by the number of leading wires and housed in said sheath.

[0026] The invention defined in claim 14 is a stent (or stent graft) locating device according to claim 13, wherein the tip of each of the number of leading wires is seamed with an elastic ring-shaped portion of a stent (or stent graft) by a joining thread.

[Brief Description of Drawings]

[0027]

Figs. 1A - 1C are partially broken side views of a stent graft locating device according to an embodiment of the invention. Fig. 1A shows the state where a stent graft fixedly encircled by a number of leading wires has been extruded from a sheath, Fig. 1B shows the state where the stent graft fixedly encircled by a number of leading wires is to be pulled into the sheath, and Fig. 1C shows the state where the stent graft fixedly encircled by a number of leading wires has been housed within the sheath.

Figs. 2A - 2D are partially broken side views of a stent graft extruded from the sheath. Fig. 2A shows the state where the leading wires encircling the stent graft are being pulled out; Fig. 2B shows the state where all the leading wires have been pulled out to locate the stent graft permanently at a diseased part; Fig. 2C shows the state where the leading wires encircling the stent graft and lead-in wires are being pulled out; and Fig. 2D shows the state where all the leading wires and the lead-in wires have been pulled out to locate the stent graft permanently at a diseased part.

Figs. 3A - 3D are conceptual views of a pushing rod for holding a number of leading wires arranged in the circumferential direction. Fig. 3A shows the pushing rod with a number of parallel leading wires arranged in the circumferential direction; Fig. 3B shows the pushing rod with a number of crossing leading wires arranged in the circumferential direction; Fig. 3C show the pushing rod with a number of parallel leading wires and auxiliary leading wires arranged in a circumferential direction; and Fig. 3D shows the pushing rode with a number of leading wires and lead-in wires arranged in the circumferential direction.

Fig. 4A is a sectional view taken in line A - A in Fig. 3A, i.e. of the pushing rod having, as a leading wire channel, a sectional ring-shaped hollow portion between an inner tube portion and an outer tube portion. Fig. 4B is a sectional view of the pushing rod with a number of leading wire channels formed at approximate regular intervals in the circumferential direction within a tube body.

Fig. 5 is a sectional view taken in line B - B in Fig. 3A.

Fig. 6 is an enlarged side view of a stent.

Fig. 7 is an enlarged side view of a stent graft.

Fig. 8 is an enlarged view for explaining the state where a stent graft fixedly encircled by a number of leading wires has been extruded from a sheath.

Fig. 9 is an enlarged view for explaining the state where lead-in wires are engaged with the stent graft held to be encircled by a number of leading wires and extruded from a sheath.

Figs. 10A - 10B are enlarged views for explaining the means for engaging the lead-in wires with the stent. Fig. 10A shows a hook and Fig. 10B shows a ring.

Fig. 11 is a partially enlarged view for explaining the stent graft shown in Fig. 8.

Fig. 12 is a perspective view of a temporarily locating type stent in which the stent body has been extruded from a catheter and expanded.

[Best Mode of Carrying out the Invention]

[0028] Referring to the drawings, an explanation will be given of various embodiments of the invention.

[0029] In Fig. 1, reference numeral 10 denotes a stent graft locating device. The stent graft locating device 10 includes a number of leading wires 1, a pushing rod 6 for holding the number of leading wires 1 arranged in the circumferential direction and a sheath 7 in which the pushing rod 6 is loaded.

[0030] As seen from Fig. 3A to 3D, the pushing rod 6 holds therein the number of leading wires 1 arranged in the circumferential direction as a bundle. The pushing rod 6 is structured in the following formats of the leading wires 1 arranged in its outside.

(1) The leading wires 1 guided from the tip of the leading wire channel (see 6D and 6c in Figs. 4A and 4B) are arranged at approximate regular intervals in the circumferential direction (Fig. 3A); (2) The leading wires 1 guided from the tip of the leading wire channel are arranged at approximate regular intervals in the circumferential direction, and cross to form a coarse mesh (M) in the vicinity of the tip of the pushing rod 6 (Fig. 3B); (3) auxiliary leading wires which are finer and shorter than the leading wires are derived, among the number of leading wires, from the tip of the leading wire channel (Fig. 3C); and plural lead-in wires 5 are derived from the tip of the leading wire channel and

engaged with the knees (11a in Fig. 9) at the terminal of the stent at approximate regular intervals by detachable engaging means 5a (Fig. 3D).

[0031] As seen from Fig. 4A, the pushing rod 6 may be composed of an inner tube 6A and an outer tube 6B so that the hollow portion of the inner tube 6A is used as a guiding wire channel 6C and the sectional ring-shaped hollow portion between the inner tube 6A and the outer tube 6B is used as a leading wire channel 6D. The guiding wire channels 6b and 6C are provided to guide the pushing rod 6 along a guiding wire (not shown). Further, as seen from Fig. 4B, the pushing rod 6 is made from e.g. a flexible tube so that the hollow portion of the tube is used as a guiding wire channel 6b and a number of leading wire channels 6c are formed within the body 6a of the tube at approximate regular intervals in the circumferential direction. The leading wires 1 are passed through the leading wire channels 6c, respectively, or through the leading wire channel 6D. These leading wires are arranged in the circumferential direction to form a bundle thereof (4 in Figs. 3A - 3D). The illustrated concrete structure of "the pushing rod which holds a number of leading wires arranged in the circumferential direction" is exemplary, and may take any other structure as long as it accords to the object of the present invention.

[0032] The auxiliary leading wires 3 may be arranged among the leading wires 2 as shown in Figs. 3B and 3D.

[0033] The leading wires 1, leading wires 2, auxiliary leading wires 3 and lead-in wires 5 may be made of stainless steel, nickel titanium, or nickel. These metallic wires are preferably used, and may be replaced by any other metallic wire as long as they are not contrary to the object of the present invention. The leading wires 1, leading wires 2, auxiliary leading wires 3 and lead-in wires 5 may be rigid plastic wires of the resin such as (1) acrylic resin, (2) polyolefin (polyethylene, polypropylene, etc.), (3) polyester, (4) polyamide, etc., or enforced plastic composed of these resins and the above metallic wire, glass fiber, carbon fiber, etc.

[0034] The leading wires 1, leading wires 2, auxiliary leading wires 3 and lead-in wires 5 have a diameter of e.g. 0.4 - 0.8 mm. Although the plurality of leading wires 1 are provided, the number thereof may be enough to hold the stent graft encircled by themselves. In Fig. 9, although nine leading wires 1 are illustrated, the number thereof may be changed according to the size of the stent graft. The plurality of the leading wires 1 are arranged at intervals in the circumferential direction within the pushing rod 6 to form a bundle. Therefore, even when they are operated from the outside of the body by pulling out/in the pushing rod 6 extended through the sheath 7 to the outside of the body, it will not be bent. The leading wires 1 has a length enough to hold the stent graft 30 in the vicinity of their tips and enable it to reach the diseased part of e.g. a blood vessel.

[0035] As shown in Fig. 1C, the stent graft 30 fixedly encircled by the plurality of leading wires may be housed within the sheath 7. In this case, as shown in Fig. 11, the tips of the plurality of leading wires may be sewed with the stent graft 30 at its elastic rings11 by joining threads 8, respectively.

In this way, the stent graft 30 can be held surely by the number of leading wires 1. These leading wires 1, which have high sliding smoothness, can be easily pulled out.

[0036] As seen from Fig. 3A, when the pushing rod 6 has a number of leading wires 1 derived from its tip and arranged at approximate intervals in the circumferential direction, the stent (or stent graft) (not shown) to be permanently located at the diseased part of the blood vessel can be expanded or contracted freely in such a way that it is squeezed out of or retracted in the tip of the sheath (7 in Figs. 1A - 1C). Therefore, if there is a positioning error, the stent (or stent graft) housed in the sheath again can be moved to and located at a safe region in the diseased part. Also, if there is impossibility of expansion, the stent (or stent graft) housed in the sheath again can be discharged again. As seen from Fig. 3B, where the pushing rod 6 has the leading wires 2 derived from its tip and arranged at approximate regular intervals in the circumferential direction, and crossing to form a coarse mesh (M) in the vicinity of the tip of the pushing rod 6, the stent graft can be wrapped in the crossing portion of the leading wires 2 and restricted strongly therein. Therefore, even when the leading wires 2 are slender, the stent graft can be housed smoothly within the sheath. As seen from Fig. 3C, where the pushing rod 6 has the auxiliary leading wires 3 which are finer and shorter than the leading wires 1 among the number of leading wires, when the stent graft is pulled in the sheath, it is possible to prevent the stent from being crinkled to be hooked by the tip of the sheath. Further, as seen from Fig. 3D, where the pushing rod 6 has a plurality of lead-in wires 5 derived from the tip of the leading wire channel (6D and 6c in Figs. 4A and 4B) and engaged with the knees (11a in the elastic ring 11 in Fig. 9) at the terminal of the stent at approximate regular intervals by detachable engaging means (hook 5a), the stent (or stent graft) can be led into the sheath 7 by the leading wires. 1 fixed on the outer surface of the stent and the detachable lead-in wires 5 attached to the terminal of the stent (knees 11a in the elastic ring 11 in Fig. 9). Also when the engaging mans has a form of a ring 5b (Fig. 10B), the same operation can be obtained.

[0037] Now referring to the drawings, an explanation will be given of the operation of the stent graft according to the invention.

[0038] As seen from Fig. 1A and Fig. 8, the stent graft 30 is encircled in the circumferential direction by the number of leading wires 1. As necessary, as shown in Fig. 11, the number of leading wires 1 are sewed with the stent graft 30 at its elastic rings 11 by junction threads 8. Thereafter, as seen from Fig. 1B, the pushing

rod 6 extended through the sheath to outside of the body is pulled gradually so that the number of leading wires 1 is retracted into the sheath 7. As shown in Fig. 1C, the stent graft 30 is folded and contracted to have a smaller diameter than the inner diameter of the sheath 7. In this way, the stent graft 30 is housed in the sheath 7. The stent graft 30 can be housed previously or immediately before use in the sheath 7.

[0039] In this case, where the pushing rod 6 has the lead-in wires 5, as shown in Figs. 10A and 10B, the engaging portion of the lead-in wire 5, i.e. hook 5a or ring 5b is engaged with the knee 11a of the elastic ring 11. In the case of the ring 5b, its one end is fixed to the inner wall of a ring-shaped fixing member 5b-1 by welding or soldering. After the ring 5b is engaged with the knee 11a of the elastic ring 11, its other end is inserted in the ring-shaped fixing member 5b-1 and a tightening member 5b-2 is screwed on the screws cut on the front surface of the ring-shaped fixing member 5b-1. The lead-in wire 5 is fixed into the inner wall of a ring-shaped lead-in wire fixing member 5b-3 by welding or soldering. The lead-in wire 5 is wound so that the lead-in wire fixing member 5b-3 is screwed on the rear surface of the ring-shaped fixing member 5b-1. The screws cut on the front surface and rear surface of the ring-shaped fixing member 5b-1 are formed by combining a right-hand thread and a left-hand thread.

[0040] The stent graft 30 housed in the sheath 7 (Fig. 1C) is inserted into the body from an incised portion of a peripheral artery (mainly femoral artery) along the guiding wire to reach the diseased part of the blood vessel. Thereafter, the far end of the pushing rod 6 is pushed so that the stent graft is squeezed into the artery to expand and located to close the aneurysm and reestablishing the bloodstream simultaneously (Fig. 1A and 1B). In this case, when it is found from the video information that unexpected accident such erroneous location and nonexpansion of the stent graft 30 has happened, the leading wires 1 are pulled so that the stent graft is housed in the sheath 7 again while it is converged (Fig. 1C). After the sheath 7 is positioned again, the stent graft 30 is located at the aneurysm in the same manner as described above. Thereafter, as shown in Fig. 2A, the leading wires 1 are pulled out of the body one by one through the pushing rod 6. Thus, as shown in Fig. 2B, the stent graft 30 is left at the diseased part of the blood vessel and permanently located there. In this way, in accordance with the present invention, by finding a safe point from the video image which is out of the dangerous point where bloodstream disorder happens when the stent graft 30 is located in the blood vessel 30, the stent graft 30 can be located in safety in the aneurysm. The leading wires 1 are pulled out of the body one by one through the pushing rod so that as shown in Fig. 2B, the stent graft 30 is left and permanently located at the diseased part in the blood vessel.

[0041] In this case, where there are auxiliary leading wires 3, like the leading wires 1, they are pulled out of the body one by one through the pushing rod 6. Further, where there are leading-in wires 5, as shown in Fig. 2C, the leading wires 1 are pulled out one by one through the pushing rod 6, and further the means, i.e. hook 5a, engaged with the terminal of the stent (knee 11a of the elastic ring 11) is taken off by pushing the lead-in wires 5 derived out of the body. Thereafter, the lead-in wires 5 are pulled out one by one through the pushing rod. Fig. 2D shows the state where the lead-in wires 5 have been pulled into the pushing rod 6. In this case, the engaging means (hook 5a) remains held at the tip of the leading wire channel (not shown). Where the engaging means is a ring 5b, the lead-in wire 5 derived out of the body is wound so that the lead-in wire fixing member 5b-3 is taken off from the ring-shaped fixing member 5b-1 at the screwed portion. Thereafter, the lead-in wires 5 are pulled out of the body one by one through the pushing rod 6.

[0042] Thereafter, the pushing rod 6 held in the sheath 7 is taken out of the body 6 (Fig. 2B and Fig. 2D) is taken out of the body together with the sheath 7.

[0043] The leading wires, auxiliary leading wires, lead-in wires, pushing rod and sheath are washed and sterilized. They will be used again.

[0044] The stent graft 30 housed within the sheath 7 can be inserted into the body 30 as follows. Previously, a guiding wire (not shown) is inserted from the incised portion of the femoral artery which is a peripheral artery to reach the incised portion of the brachial artery through the diseased part of the blood vessel. The one end of the guiding wire derived from the incised portion of the femoral artery is passed through the guiding wire channel 6b (6C) of the pushing rod. By guiding the stent graft 30 housed within the sheath 7 using the guiding wire, it can be inserted from the incised portion of the femoral artery to reach the diseased part of the blood vessel.

[0045] In this way, the stent graft 30 is permanently located at the diseased part within the blood vessel so that expansion of the artery stenosis lesion and closing of the aneurysm are carried out while the blood stream is reestablished.

[0046] The details of the stent 20 are shown in Fig. 6. The stent has an outer diameter of 20 - 40 mm when it is expanded and has a length of 30 - 100 mm. The stent 20 has a plurality (three in the drawing) of elastic rings 11 each formed in ring shape by a metallic wire bent in zigzag. The elastic rings are arranged at regular intervals in the axial direction of the stent. Around the elastic ring 11, coupling wires 12 are arranged at regular intervals in the circumferential direction. These coupling wires 12 are welded or soldered on the elastic rings 11 at their points of intersection of them. The elastic rings 11 and the coupling wires 12 are made of the metal having rigidity such as stainless steel, titanium, nickel titanium, etc. The metallic wire has a diameter of about 0.4 - 0.8 mm. The stent 20 may be constructed of

a mesh of these metallic wires (not shown).

[0047] The details of the stent graft are shown in Fig. 7. The stent graft 30 is structured so that the stent 20 described above is inserted in a graft 13 (artificial blood vessel) of polyester or Teflon (PTFE) and the graft 13 is seamed with the elastic rings 11 by threads of polypropylene (not shown).

[0048] The mode of carrying out the invention was explained mainly on the stent graft, the invention can be applied to the stent in a similar manner.

[Embodiment]

[0049] Referring to the drawings, an embodiment of the invention will be explained below.

[0050] As seen from Fig. 6, a stent 20 is composed of three elastic rings 11 each made of a metallic wire of a shape memory alloy (NITI) and formed in a spring shape, which are coupled by means of coupling wires 12 each made of the metallic wire by welding or soldering. The stent 20 is sewed into a graft (artificial blood vessel) 13 of Teflon (PTFE) as shown in Fig. 7 to form a stent graft 30. On the other hand, the guiding wire (not shown) is previously inserted from the incised portion of a peripheral artery (mainly femoral artery) in a thoracic aortic aneurysm model to reach the incised portion of the brachial artery through the diseased part of the blood vessel. The guiding wire derived from the incised portion of the femoral artery is passed into the hollow portion of the stent graft 30 and into the guiding wire channel 6b (6C) (Figs. 4A and 4B) of the pushing rod 6 in the stent graft locating device 10 as shown in Fig. 1A. The far end of the guiding wire is extended out of the sheath 7.

[0051] The stent graft 30 is fixedly encircled by nine leading wires 1. Two lead-in wires 5 are removably attached to the terminal of the stent (knees 11a of the elastic ring 11) at regular intervals by means of the hooks 5a. The pushing rod 6 is pulled so that the stent graft 30 encircled by the nine leading wires 1 and two lead-in wires 5 is folded to have a diameter smaller than the internal diameter (18 - 20 French (6 mm - 6.667 mm))of the sheath 7. In this case, the number of leading wires 1 and lead-in wires 5 are arranged in the circumferential direction. The far end of the bundle 4 of the leading wires 1 and lead-in wires 5 is extended out of the sheath 7 through the leading wire channel 6c of the pushing rod 6.

[0052] As shown in Fig. 1C, the stent graft 30 housed in the sheath 7 is inserted from the incised portion of the peripheral artery along the guiding wire to reach the diseased part of the blood vessel. Thereafter, as shown in Figs. 1B and 1C, the stent graft encircled by the number of leading wires is extruded from the tip of the sheath 7 by the pushing rod 6 so that it is discharged into the diseased part of the blood vessel and temporarily located there, otherwise recovered into the sheath 7 by the lead-in wires 5 and temporarily housed therein. Thus, the safe point is found from the video image which is out of the dangerous point where bloodstream disorder happens when the stent graft 30 is located in the blood vessel. Thereafter, as shown in Fig. 2C, with the stent graft 30 expanded at the safe point, the leading wires 1 and lead-in wires 5 are pulled out one by one so that as shown in Fig. 2D, the stent graft 30 is permanently left at the diseased part in the blood vessel. When liquid is circulated through the thoracic aortic aneurysm model, a good operation result was acquired.

[Industrial Applicability]

[0053]

(1) In accordance with the invention, the expansion, contraction, movement and recovery of the stent (or stent graft) to be located permanently can be controlled freely outside a human body. Therefore, by pulling out or in the stent (or stent graft) from the tip of the sheath at the diseased part in the blood vessel, i.e. freely expanding or contracting it, it can be located surely at a safe point.

(2) In accordance with the invention, when it is found that the stent (or stent graft) to be used is not suited to medical treatment, it can be recovered. This improves safety of the treatment.

(3) In accordance with the invention, since the blood vessel can be treated using the stent (or stent graft) which is right in an operation invasion, it is possible to reduce pain or burden for a patient in the treatment for the blood vessel and the cost therefor. Therefore, the treatment using the stent (or stent graft) can also be applied to the treatment of the aneurysm which has been out of application so that an effective treatment can be provided for a large number of patients of the aneurysm.

(4) The present invention can be applied to the stent (or stent graft) having various structures and sizes which are different according to manufactures and objects of use. The stent according to the invention can be recovered for its reuse, thus providing great economic effects.

(5) In accordance with the present invention, the pushing rod has a large number of parallel leading wires which are derived from the tip of the pushing rod and arranged in the circumferential direction, and these leading wires cross to form a coarse mesh in the vicinity of the tip of the pushing rod. Because of this configuration, the entire stent graft can be encompassed by a small number of leading wires, and the stent graft can be smoothly recovered into the sheath.

(6) In accordance with the present invention, since the pushing rod has auxiliary leading wires which are shorter than the leading wires 1 among the number of leading wires, when the stent graft is pulled in the sheath, it is possible to prevent the

stent from being crinkled to be hooked by the tip of the sheath.

(7) In accordance with the present invention, the stent (or stent graft) can be pulled into and housed in the sheath using the detachable lead-in wires which are engaged with the knees of the elastic ring at the terminal of the stent (or stent graft) by the engaging means such as a hook or ring. Therefore, the discharge/expansion and the contraction/housing of the stent (or stent graft) can be repeated. Accordingly, the stent (or stent graft) can be located at a more safe point swiftly.

Claims

1. A stent (or stent graft) locating device comprising a number of leading wires, a pushing rod for holding the number of leading wires in its circumferential direction and a sheath for loading the pushing rod therein.

2. A stent (or stent graft) locating device according to claim 1, wherein said pushing rod is composed of an inner tube and an outer tube, a hollow portion of said inner tube is used as a guiding wire channel and another sectional ring-shaped hollow portion between said inner tube and said outer tube is used as a leading wire channel.

3. A stent (or stent graft) locating device according to claim 1, wherein said pushing rod is constructed of a single tube, a hollow portion of said tube is used as a guiding wire channel and a plurality of leading wire channels are arranged in a body of said tube at approximate regular intervals in its circumferential direction.

4. A stent (or stent graft) locating device according to claim 1, 2 or 3, wherein said pushing rod has a plurality of leading wires which are derived from the tip of a leading wire channel and scattered at approximate regular intervals in the circumferential direction.

5. A stent (or stent graft) locating device according to claim 1, 2 or 3, wherein said pushing rod has a plurality of leading wires which are derived from the tip of a leading wire channel and scattered at approximate regular intervals in the circumferential direction, and said plurality of leading wires cross in the vicinity of the tip of said pushing rod so as to form a coarse mesh.

6. A stent (or stent graft) locating device according to claim 4 or 5, wherein said pushing rod has a plurality of auxiliary leading wires which are finer and shorter than the leading wires are derived, among the number of leading wires, from the tip of said leading wire channel.

7. A stent (or stent graft) locating device according to claim 4, 5 or 6, wherein said pushing rod has plural lead-in wires which are derived from the tip of the leading wire channel and engaged with the knees at the terminal of the stent at approximate regular intervals by detachable engaging means.

8. A stent (or stent graft) locating device according to claim 7, wherein said engaging means is a hook formed by bending the tip of each of said lead-in wires.

9. A stent (or stent graft) locating device according to claim 7, wherein said engaging means is a ring screwed into the tip of each of said lead-in wires.

10. A stent (or stent graft) locating device according to any one of claims 1 to 9, wherein said leading wires are metallic wires of stainless steel, titanium nickel or nickel.

11. A stent (or stent graft) locating device according to claim 6, wherein said auxiliary leading wires are metallic wires of stainless steel, titanium nickel or nickel.

12. A stent (or stent graft) locating device according to any one of claims 7 to 9, wherein said lead-in wires are metallic wires of stainless steel, titanium nickel or nickel.

13. A stent (or stent graft) locating device according to any one of claims 1 to 12, wherein said stent (or stent graft) is encircled by the number of leading wires and housed in said sheath.

14. A stent (or stent graft) locating device according to claim 13, wherein the tip of each of the number of leading wires is seamed with an elastic ring-shaped portion of a stent (or stent graft) by a joining thread.

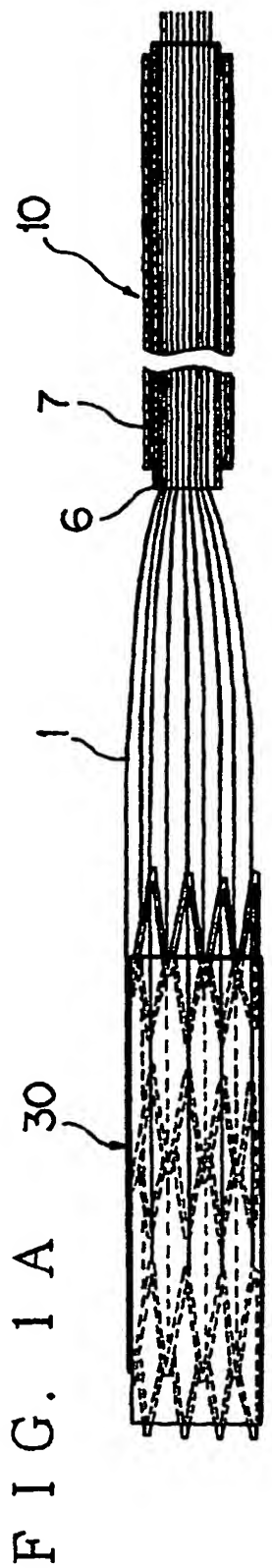

FIG. 1A

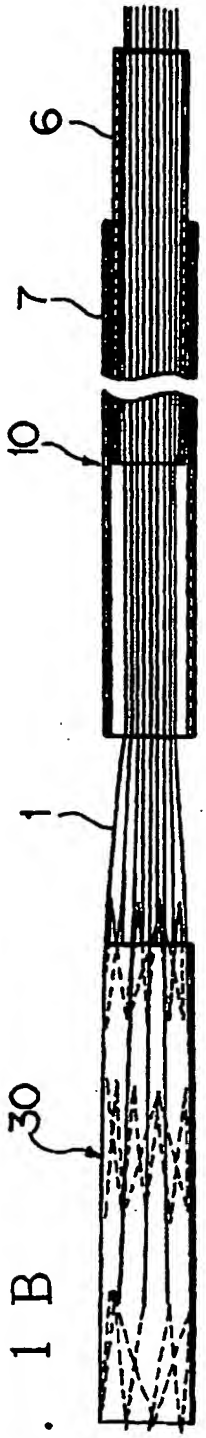

FIG. 1B

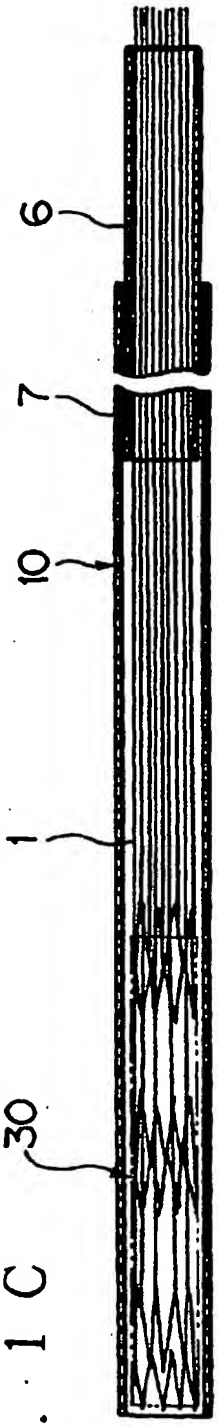

FIG. 1C

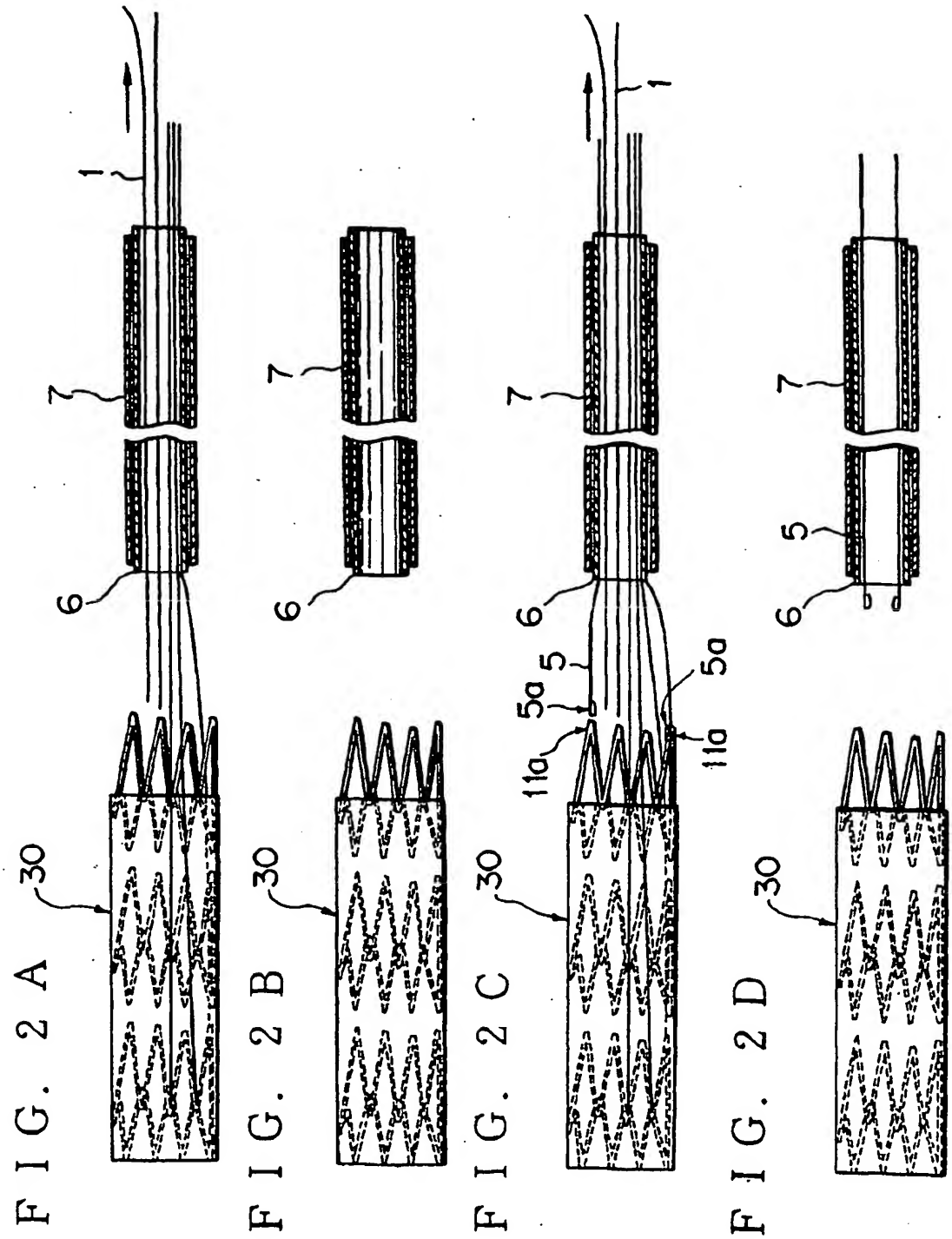

FIG. 2A

FIG. 2B

FIG. 2C

FIG. 2D

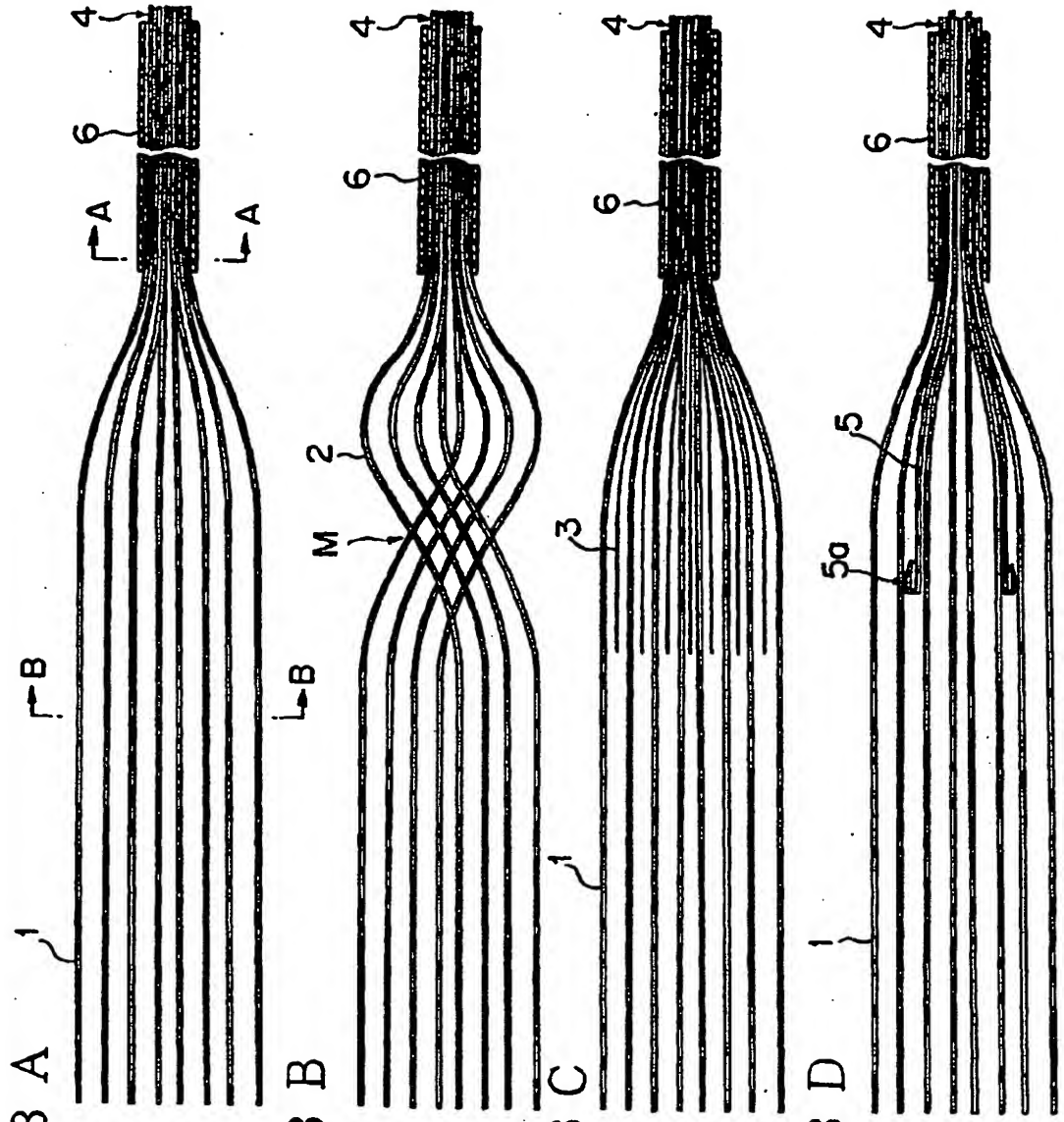

FIG. 3A

FIG. 3B

FIG. 3C

FIG. 3D

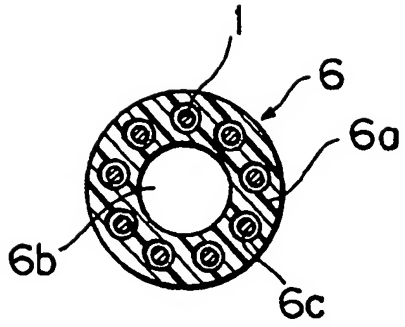

FIG. 4A

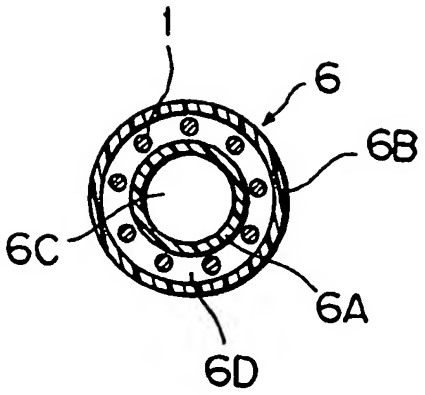

FIG. 4B

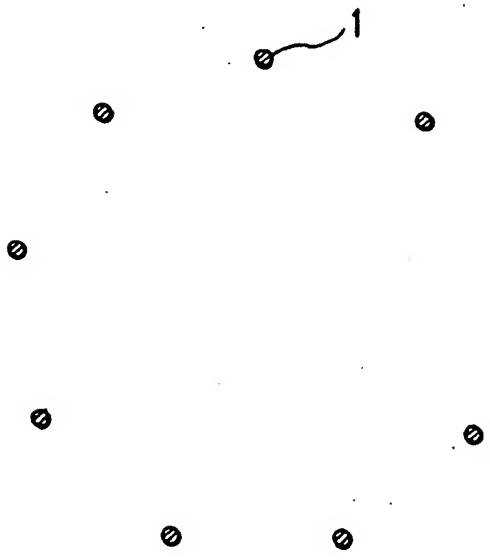

FIG. 5

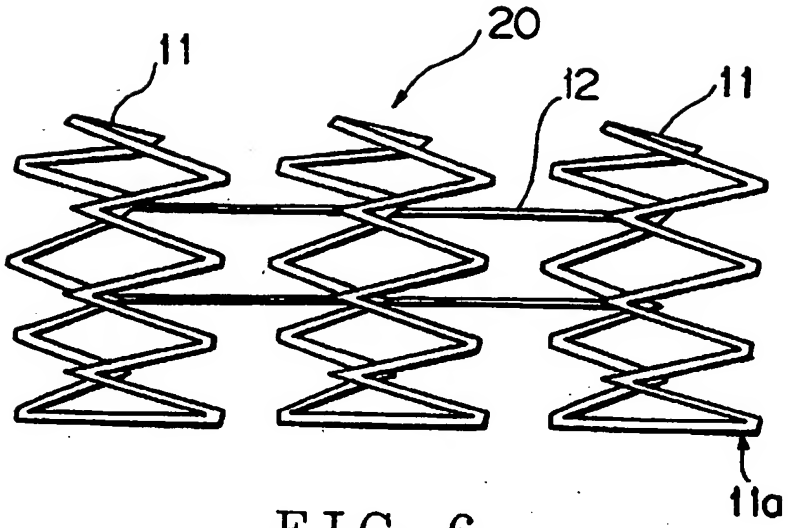

FIG. 6

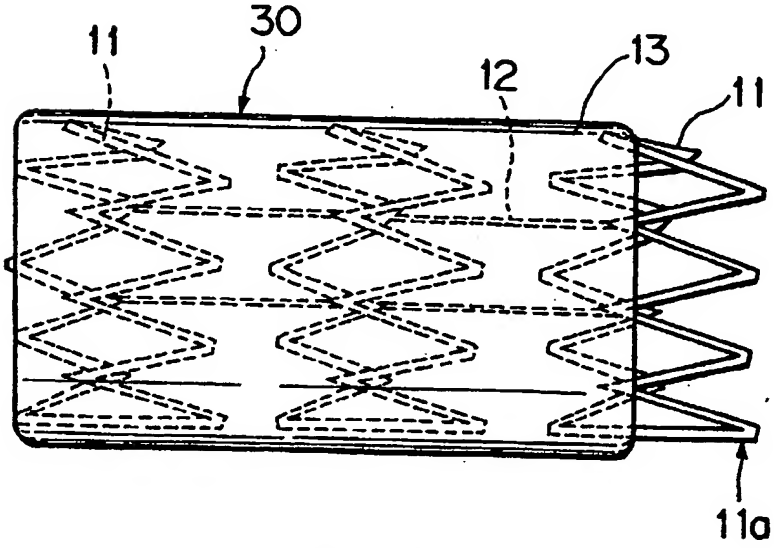

FIG. 7

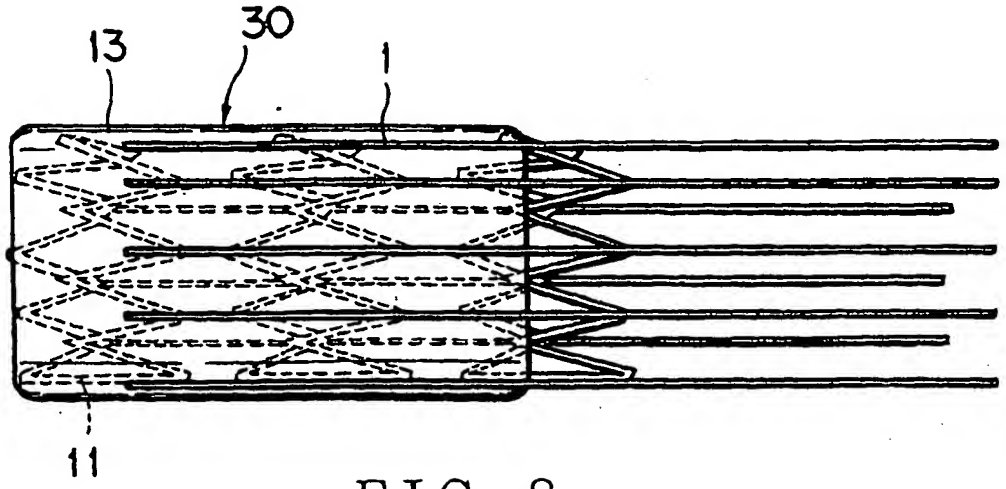

FIG. 8

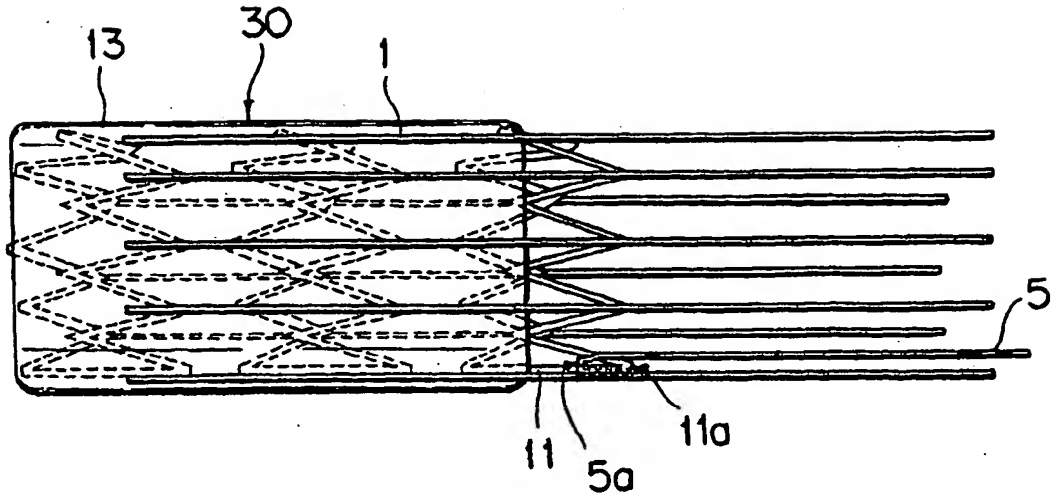

FIG. 9

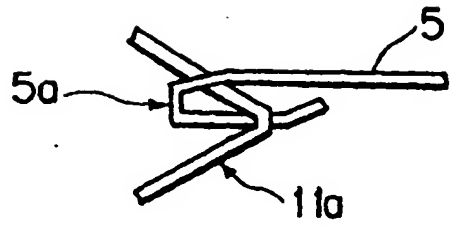

FIG. 10 A

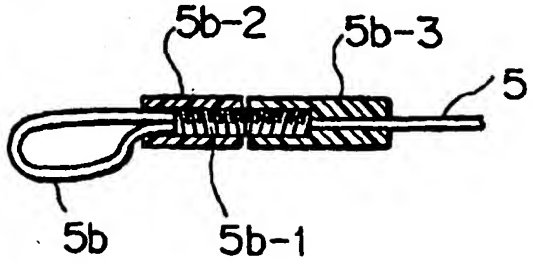

FIG. 10 B

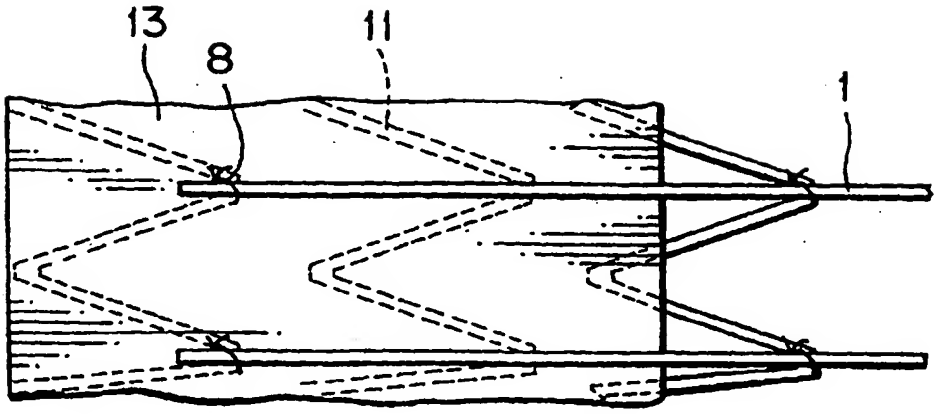

FIG. 11

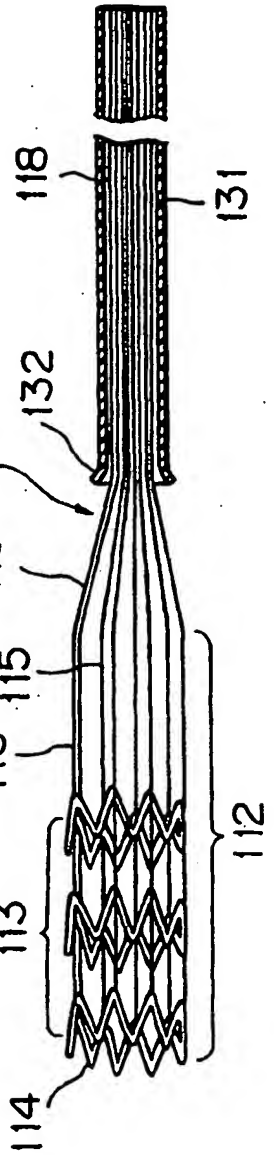

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP99/00824

A. CLASSIFICATION OF SUBJECT MATTER
Int.Cl[6] A61M29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int.Cl[6] A61M29/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1926-1999 Toroku Jitsuyo Shinan Koho 1994-1999
Kokai Jitsuyo Shinan Koho 1971-1999 Jitsuyo Shinan Toroku Koho 1996-1999

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	JP, 7-504595, A (Schneider(USA),Inc.), 25 May, 1995 (25. 05. 95),	1, 4, 10
A	All items & WO, 94/00178, A & EP, 647147, A & US, 5653684, A	2, 3, 5-9, 11-14
A	JP, 6-98939, A (Nippon Shiruko Tex K.K.), 12 April, 1994 (12. 04. 94), All drawings (Family: none)	1
A	JP, 2-172456, A (Kato Hatsusjo Kaisha,Ltd.), 4 July, 1990 (04. 07. 90), All drawings (Family: none)	1
A	JP, 5-212121, A (Kanji Inoue), 24 August, 1993 (24. 08. 93), All drawings (Family: none)	1
PY	WO, 98/56449, A1 (Shin Ishimaru), 17 December, 1998 (17. 12. 98), Full text & JP, 10-337333, A	1

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"B" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 May, 1999 (24. 05. 99)	1 June, 1999 (01. 06. 99)
Name and mailing address of the ISA/ Japanese Patent Office	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP99/00824

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, 92/18195, A1 (Shturman Technologies Inc.), 29 October, 1992 (29. 10. 92), Full text & JP, 06-509722, A	1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)